

## U.S. PATENT DOCUMENTS

|                 |         |                     |
|-----------------|---------|---------------------|
| 5,648,350 A     | 7/1997  | DeLignieres         |
| 5,651,973 A     | 7/1997  | Moo-Young et al.    |
| 5,654,337 A     | 8/1997  | Roentsch et al.     |
| 5,656,286 A     | 8/1997  | Miranda et al.      |
| 5,708,038 A     | 1/1998  | Davis               |
| 5,716,638 A     | 2/1998  | Touitou             |
| 5,719,197 A     | 2/1998  | Kanios et al.       |
| 5,723,114 A     | 3/1998  | Thornfeldt et al.   |
| 5,744,162 A     | 4/1998  | Okabe et al.        |
| 5,760,096 A     | 6/1998  | Thornfeldt et al.   |
| 5,770,606 A     | 6/1998  | El Rashidy et al.   |
| 5,776,923 A     | 7/1998  | Labrie              |
| 5,788,983 A     | 8/1998  | Chien et al.        |
| 5,807,849 A     | 9/1998  | Labrie              |
| 5,807,957 A     | 9/1998  | Samour et al.       |
| 5,837,289 A     | 11/1998 | Grasela et al.      |
| 5,847,128 A     | 12/1998 | Martin et al.       |
| 5,855,905 A     | 1/1999  | Oettel et al.       |
| 5,874,074 A     | 2/1999  | Smith               |
| 5,908,619 A     | 6/1999  | Scholz              |
| 5,908,638 A     | 6/1999  | Huber et al.        |
| 5,932,227 A     | 8/1999  | Higo et al.         |
| 5,955,455 A     | 9/1999  | Labrie              |
| 5,968,919 A     | 10/1999 | Samour et al.       |
| 6,010,716 A     | 1/2000  | Saunal et al.       |
| 6,019,997 A     | 2/2000  | Scholz et al.       |
| 6,037,346 A     | 3/2000  | Doherty, Jr. et al. |
| 6,075,028 A     | 6/2000  | Graham              |
| 6,077,841 A     | 6/2000  | Sui et al.          |
| 6,087,368 A     | 7/2000  | Macor et al.        |
| 6,117,446 A     | 9/2000  | Place               |
| 6,127,363 A     | 10/2000 | Doherty et al.      |
| 6,156,753 A     | 12/2000 | Doherty et al.      |
| 6,238,284 B1    | 5/2001  | Dittgen et al.      |
| 6,299,900 B1    | 10/2001 | Reed et al.         |
| 2001/0018073 A1 | 8/2001  | Dittgen et al.      |
| 2001/0023261 A1 | 9/2001  | Ryoo et al.         |
| 2001/0033870 A1 | 10/2001 | Luo et al.          |
| 2001/0036483 A1 | 11/2001 | Luo et al.          |
| 2001/0051166 A1 | 12/2001 | Luo et al.          |

## OTHER PUBLICATIONS

- Longstreth, et al., *Transdermal Testosterone Pharmacokinetics Remain Unchanged With Prolonged Treatment*, Unimed Pharmaceuticals (Oct. 31, 2000).
- Ringham, et al., *Dose Proportionality and Systemic Bioavailability of a Testosterone Topical Gel In Hypogonadal Men*, Unimed Pharmaceuticals (Oct. 31, 2000).
- Miller, et al., *Androgen Deficiency in Women with Hypopituitarism*, *The Journal of Clinical Endocrinology & Metabolism*, vol. 86, No. 2, pp. 561-567 (2001).
- Veldhuis, et al., *Muting of Androgen Negative Feedback Unveils Impoverished Gonadotropin-Releasing Hormone/Luteinizing Hormone Secretory Reactivity in Healthy Older Men*, *The Journal of Clinical Endocrinology & Metabolism*, vol. 86, No. 2, pp. 529-535. (2001).
- Swerdloff, et al., *Long Term Pharmacokinetics of Transdermal Testosterone Gel Versus Testosterone Patch in Hypogonadal Men*, 2347 Male Reproductive Poster Session, Board 578 (Jun. 22, 2000).
- Wang, et al., *Effects of Transdermal Testosterone Gel on Bone Turnover Markers and Bone Mineral Density in Hypogonadal Men*, 2348 Male Reproductive Poster Session, Board 579 (Jun. 22, 2000).
- Wang, et al., *Effects of Transdermal Testosterone Gel on Bone Turnover Markers and Bone Mineral Density in Hypogonadal Men*, *Clinical Endocrinology*, vol. 54, pp. 1-13 (2001).
- Wang, et al., *Transdermal Testosterone Gel Improves Sexual Function, Mood, Muscle Strength, and Body Composition Parameters in Hypogonadal Men*, *Basic Science: Reproduction-Gonadal Control (Male)*, Male Reproduction Oral Session, No. 1360 (Jun. 24, 2000).
- Unimed Pharmaceuticals' Androgel Shows Solid Promise for Men*; Fertility Industry News, www.INC IID.com (Aug. 19, 1998).
- Bentley Pharmaceuticals Announces License Agreement for Its Topical Testosterone Gel Formulation*; Li, www.UVentures.com (Dec. 18, 2000).
- Ruggs, *Unimed Begins Pivotal Clinical Trial For Innovative Testosterone Gel*, Unimed News Release, pp. 1-2 (Mar. 31, 1997).
- Androgel 1% (testosterone gel) CIII.; www.Androgel.com, pp. 1-2.
- Wang, et al., *Effects of Transdermal Testosterone Gel on Bone Turnover Markers and Bone Mineral Density in Hypogonadal Men*, *Clinical Science: Reproduction (Male)-Prostate*, Male Reproduction Poster Session, No. 2348 (Jun. 22, 2000).
- Swerdloff, et al., *Long Term Pharmakinetcs of Transdermal Testosterone Gel Versus Testosterone Patch in Hypogonadal Men*, *Clinical Science: Reproduction (Male)-Prostate*, Male Reproduction Poster Session, No. 2347 (Jun. 22, 2000).
- Trials for the Treatment of Wasting*, AIDS Treatment Data Network, www.aidsinfonyc.org (Downloaded Oct. 8, 1998).
- De Lunardo, et al., *Determination of Acceptability of 2 Cutaneous Estradiol Gels, In A Dose of 1.5 mg Daily*, *J. Gynecol. Obstet. Biol. Reprod. (Paris)*, vol. 29, No. pp. 509-516, (Sep. 2000).
- Zartarian, et al., *Comparative Evaluation of the Acceptability of a New Estradiol Gel TX11323(A) and a Reference Gel*, *J. Gynecol. Obstet. Biol. Reprod. (Paris)*, vol. 25, No. 5, pp. 451-456 (1996).
- Simon, et al., *The Absorption of Oral Micronized Progestrone: The Effect of Food, Dose Proportionality, and Comparison With Intramuscular Progesterone*, *Fertility and Sterility*, vol. 60, No. 1, pp. 26-33 (Jul. 1993).
- Vaubourdolle, et al., *Effect of Dihydrotestosterone on the Rate of Ethanol Elimination in Healthy Men*, *Alcohol Clin. Exp. Res.*, vol. 15, No. 2, pp. 238-240 (Mar. 1991).
- Fournier, et al., *Value of Percutaneous Estrogen Solution in Stopping Lactation*, *Rev. Fr. Gynecol. Obstet.*, vol. 85, No. 12, pp. 715-719 (Dec. 1990).
- Simon, et al., *Percutaneous Absorption of 17 Beta-Estradiol in Ovariectomized Rhesus Monkeys: Skin and Serum Pharmacokinetics*, *Fertility and Sterility*, vol. 53, No. 3, pp. 561-565 (Mar. 1990).
- Rodriguez, *Study of Drug to Preserve Lean Muscle Mass Recruiting Patients*, ALPA 9701: Study Recruiting Patients, www.apla.org (Downloaded Oct. 8, 1998).
- HIV Wasting Treatment: Nandrolone Decanoate, www.hivinsite.ucsf.edu (Aug. 1, 1995).
- Vergel, *Anabolic Steroids: A Practical Guide*, CRIA Update, vol. 7, No. 3 (Summer 1998).
- HIV Wasting Syndrome, www.thebody.com (May 1997).